Supporting Statement for OMB Review
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Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative Trans Fat Disclosures on the Nutrition Facts Panel (NFP)

Submitted by:

Office of Scientific Analysis and Support
Division of Market Studies
Food and Drug Administration
Department of Health and Human Services

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Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative Trans Fat Disclosure on the Nutrition Facts Panel (NFP)

Supporting Statement for Information Collection Request

A. JUSTIFICATION

A.1 Necessity for the Information Collection

The Food and Drug Administration (FDA) regulates the labeling of food products under the Food, Drug and Cosmetic Act of 1938 (FDCA) and the Nutrition Labeling and Education Act of 1990 (NLEA).

In November 1999, FDA proposed (64 FR 62746) to amend regulations on nutrition labeling to require that the amount of trans fatty acids (trans fat) present in a food be included on the Nutrition Facts Panel (NFP). The purpose of the proposal was to better enable consumers to understand the contribution of the product to a total diet as mandated by NLEA. In the proposal, FDA agreed with the argument made by a petitioner that consumers need to know the levels of trans fat in a food product to be able to judge the nutritional significance of that product in the context of the total diet. Dietary trans fatty acids, like saturated fats, have adverse effects on blood cholesterol levels. The public health recommendation is to keep intake as low as possible. The agency initially proposed that trans fat levels be disclosed on the NFP as part of the saturated fat declaration (combining the gram amount of sat fat and trans fat and recalculating the percent DV to include trans fat). A footnote was proposed to indicate the amount of trans fat included in the combined amount.

Comments to the proposal argued against combining trans and saturated fat amounts into a single amount on grounds that there was no scientific or public health basis for applying the saturated fat DV to the combined amount. In November 2002, the agency reopened the comment period and proposed that the declaration of trans fat on the NFP be on a separate line immediately under that for saturated fat without an accompanying percent DV declaration, but with an accompanying footnote stating, "intake of trans fat should be as low as possible". The purpose of the accompanying footnote was to ensure that the trans fat information "be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet."

Several comments challenged the agency's assumptions about how the accompanying footnote would be interpreted by consumers. Three separate research studies were submitted (CSPI, Conagra, IFIC) that showed limitations in the public's ability to use and understand the quantitative trans fat information in the presence of the proposed footnote. These studies provide some empirical evidence to support arguments made in a number of other comments that the

proposed footnote might distort the appropriate understanding of the dietary significance of trans fat relative to other fatty acids, thereby causing the public to make poorer, rather than better, product choices. Since this is the opposite of the intended effect of the proposed footnote, the agency has determined that a systematic study is required to assess what kinds of footnotes or other decision aids are best able to help the public use the quantitative trans fat information in the NFP "to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet."

On July 11, 2003 (68 FR 41434), FDA issued a final rule that requires disclosure of quantitative trans fat information on the Nutrition Facts Panel on a separate line without any accompanying footnote. At the same time, the agency issued a ANPR asking for comments about possible footnotes to help consumers better understand trans fat declarations on the product label. The Federal Register Advance Notice of Proposed Rulemaking July 11, 2003 (68 FR 41507)**:** Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements, states that the agency is seeking information about whether it should consider statements about trans fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel to enhance consumers' understanding about such cholesterol-raising lipids and how to use disclosed information on the label to make healthy food choices. The proposed study is intended to evaluate the ability of several possible footnotes and cuing schemes to enable consumer heart-healthy food choices in order to provide empirical support for possible policy decisions about the need for such requirements and the appropriate form they should take.

The consumer behavior problem demonstrated by the CSPI, Conagra and IFIC studies is that when consumers look at the NFPs of two products with different fatty acid profiles in the presence of the proposed footnote, they become more likely to choose the product with less trans fat even when the other product has an arguably better (i.e., healthier) fatty acid profile. The CSPI study compared the effect of the proposed footnote with a no footnote condition and a modified footnote that said "Combined total intake of saturated and trans fats should be as low as possible." The quality of product choices (percent respondents who choose the healthier product/percent respondents who choose the less healthy product) declined in the presence of the proposed foodnote, but improved with the modified footnote. In the Conagra study, the proposed footnote condition was the only one tested. Respondents who made the "wrong" product choice, i.e., choose the product with more total fat or more combined saturated and trans fat, tended to justify their choice in terms of the selected product having less trans fat. It is also noteworthy that two thirds of respondents indicated they did not know how to interpret (and therefore how to apply) the proposed footnote information. In the IFIC study, respondents were asked to compare two products repeatedly as more information was revealed about the two products (including trans fat information and footnotes). The quality of respondent choices deteriorated as more information was given that focused their attention on trans fat levels.

Each of these studies have serious limitations that render their findings suggestive but not definitive from the perspective of evaluating policy options. The CSPI and Conagra studies employ a much too restricted range of products to generalize confidently to the full range of products in the marketplace. The CSPI study does not use realistic label presentations. The IFIC study uses within-subject manipulations of information conditions subject to experimental demand biases that may compromise the validity of its findings. Moreover, none of the studies evaluates a broad range of possible policy options the might be considered applicable to the problem of how best to inform consumers about the dietary significance of trans fat information on the food label.

It may be that low population levels of knowledge about trans fat, documented in recent consumer surveys (FDA HDS surveys in 1995 and 2002), play a crucial role in explaining the unexpected effects of trans fat footnotes. Several recent labeling studies show that prior knowledge levels influence how consumers interpret and make inferences from label information. Low compared to high prior knowledge levels tend to increase the impactfulness of label information and increase the likelihood of misleading inferences. (Roe, Derby and Levy, 1996; Burke, Milberg and Moe, 1997).

The information objectives for the study are as follows:

1. Evaluate possible dietary guidance footnotes and related labeling options-(i.e., possible footnote cuing schemes) to determine whether and to what extent, these labeling options contribute to misunderstanding or misapplying the quantitative trans fat information declared on the NFP.

2. Assess effectiveness of labeling options using measures that represent consumer understanding and ability to use quantitative information about trans fat and other fatty acids in realistic product selection and usage situations

3. Assess the role that an individual's prior knowledge about the nutritional significance of trans fat plays in determining the impact of trans fat related label information.

4. Assess respondent's self perceptions of the usefulness of the footnote in helping them interpret fatty acid information on the NFP.

A2. How, By Whom and the Purpose for Collecting This Information

In order to achieve its intended objectives, the study employs an experimental design where effects of various proposed footnote conditions are estimated by exposing random samples of subjects to controlled experimental conditions. Stimulus differences between

conditions consist entirely of the experimentally manipulated label treatments that embody different possible versions of proposed footnotes. Individual differences are randomly distributed across conditions allowing for statistically valid tests of observed treatment effects between conditions.

The study uses an internet panel methodology which has proved substantially equivalent to mall intercept methodologies in that it allows visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. The study will use as its sample frame a large nationally representative consumer panel with 600,000 households.

Participants will be adults, age 18 and older, who are recruited for a study about foods and food labels. Each participant will be randomly assigned to one of the 42 experimental conditions.

They will be asked to thoroughly review the package labeling of products presented to them in pairs and then answer questions about the product's perceived health benefits, choice preferences, risk/benefit tradeoffs, and other questions.

Manipulations

Product Types/Fatty Acid Profile

It is necessary to demonstrate the generalizability of observed effects across a representative range of product types to ensure that some unique aspect of a certain product type is not responsible for the observed effects. We propose to include three product types in the study that represent typical kinds of product that contain significant amounts of trans fatty acids.

The three categories and the proposed product A and product B fatty acid profiles are given below.

	Cookies		Margarine		Frozen Dinner	
	Prod A	Prod B	Prod A	Prod B	Prod A	Prod B
Tfat	14g	12g	10g	12g	22g	22g
Sfat	10g	6g	2g	4g	11g	5g
Trfat	0g	2g	3g	0g	0g	7g
PolyF			3g	5g		
MonoF			2g	4g		
Chol	0mg	0mg	0mg	0mg	150mg	0mg

Footnote Options

1. No footnote. Final rule (as of June 2003)—required trans disclosure on NFP on a separate line without any %DV declaration and without any footnote (control).

2. Required trans disclosure on NFP on a separate line without any %DV declaration but with an asterisk by trans fat that refers to an accompanying footnote, "Intake of trans fat should be as low as possible" (Footnote option 1)

3. CSPI proposed option—same as 2 above, but with an asterisk by saturated fat and trans fat with the footnote worded, "Combined intake of saturated and trans fat should be as low as possible" (Footnote option 2)

4. Same as 3 above, but with the footnote worded, "Combined intake of saturated and trans fat should be kept as low as possible while maintaining a nutritionally adequate diet." (Footnote option 2a).

5. Same as 3 above, but with the footnote worded, "Combined intake of saturated and trans fat should be kept low." (Footnote option 2b)

6. An asterisk by saturated fat, trans fat, and cholesterol with the asterisked footnote worded, "Intake of saturated fat, trans fat and cholesterol should be kept low" (Footnote option 3)

7. Same as 6 above except the footnote is worded. "Intake of cholesterol raising substances should be kept low." (Footnote 3b)

Full Information/No Information Treatment

Given the current low level of trans fat knowledge in the population, and the avowed aim of the trans fat labeling policy to increase such knowledge, we propose to systematically manipulate trans fat knowledge of respondents. Respondents in the full information condition will be briefed about relevant facts concerning trans fat prior to seeing any product labels. Respondents in the no information will not be given any information about trans fat. The manipulation of prior knowledge will allow evaluation of the effectiveness of policy options under conditions approximating the current distribution of knowledge in the population as well as conditions representing familiarity with the nutritional consequences of the trans fat. .

Experimental Design

The basic experimental design is

> Information Treatment (Full/None) X Product Type (Cookies, Margarine, Frozen Dinner) X Footnote Conditions (7) resulting in a fully crossed design with 42 conditions.
>
> We conclude that 60 subjects per cell, 2560 subjects in all, will provide adequate power to identify small to medium size effects (i.e., r = .15-30) for all main effects and first order interactions with power = (1-beta) well

in excess of .80. Power for second and third order interactions will necessarily be smaller, but even for third order interactions power = .65.

The Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS) is the primary user of this information. The information provided by the study will inform regulatory initiatives announced in the June 2003 ANPR. The results will be made available as part of the docket so that all interested parties can comment on and benefit from the findings.

A3. Use of Technology to Reduce the Burden on the Public

The study relies on a commercially available internet panel to be the sample frame from which samples of respondents can be randomly drawn to be assigned to condition. Data collection will take place over the internet.

A4. Identification and Use of Duplicate Information

The proposed study is based in part on several studies submitted as comments to the trans fat rule (CSPI, 2003; IFIC, 2003, Conagra, 2003). Some of the measures used in the present study are based directly on measures used in that research, particularly the two product choice task measures. The study addresses a number of flaws in these previous research studies, including the inclusion of necessary control conditions, testing a wider range of possible footnote options, using more realistic labels, and evaluating prior knowledge effects, that will strengthen the validity and generalizability of results for the policy process.

A5. FDA's Efforts to Reduce Burden on Small Business

There is no impact on small business from this data collection.

A6. Impact of Not Collecting This Information or Collecting Information Less Frequently

This study is a one-time data collection. FDA is trying to finalize its trans fat regulations in anticipation of the 2006 effective date for mandatory disclosure of trans fat on the NFP. Possible requirements for clarifying footnotes and the form and content of educational initiatives intended to help consumers better understand and use trans fat information will necessarily be informed by the findings of the proposed study.

A7. Special Circumstances That Occur When Collecting This Information

No special circumstances.

A8. Identification of Outside FDA sources

Consumer understanding of trans fat declarations has been the subject of extensive public comments since the November 1999 publication of the proposed rule. Comments were carefully considered in the formulation of the present research design. Important features of the proposed study are, in fact, based on preliminary research from industry, consumer groups and public health organizations.

The revised proposal was sent to three external peer reviewers at academic institutions with expertise in consumer research and labeling topics. The reviewers provided comments on the study design and questionnaire. The proposed study incorporates the comments from the peer reviewers.

Peer Reviews:

1. Manoj Hastak, PhD
   Associate Professor and Chair of Marketing Department
   Kogod School of Business
   American University, Washington, DC
2. Alan Mathios, PhD
   Associate Professor and Department Chairperson
   Department of Policy Analysis and Management
   Cornell University, Ithaca, NY
3. Debra Ringold, PhD
   Associate Dean and Professor of Marketing
   Atkinson School
   Willamette University, Salem, Oregon

On November 10, 2003, (68 FR 63801) FDA published an emergency request for comment on this information collection.

A9. Payment or Gifts Offered to

The proposed study uses an existing consumer internet panel as its sample frame. Participants complete interview instruments without specific reimbursement, but they receive small tokens of appreciation and are eligible for prizes as a consequence of their ongoing participation.

A10. Method of Ensuring Confidentiality

No identifying information about individual respondents is included in the data file or other information provided to the government by the contractor

A11. Use of Sensitive Questions

This study does not include any sensitive questions.

A12. Burden Hours and Cost Associated With This Information Collection.

The total sample is 2,560. Based on past experience, the interview length will average 15 minutes. The estimates of the interview length have been adjusted downward from the estimate in the emergency notice, based on the revised questionnaire.

Estimated Annual Reporting Burden[1]

Number of	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2,560	1	2,560	.25	640

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

A13. Annual Cost Estimate to Respondents

There are no costs associated with this data collection outside the burden reflected in A12.

A14. Annual Cost Estimate to FDA

FDA has contracted with Synovate/Market Facts for data collection services. Peer reviewers were paid under personal services contracts.

Contractor estimated cost =	$198,800
Peer reviewers =	$ 5,700
Total =	$204,500

A15. Changes from Previous Approval

This is a new project.

A16. Publishing the Results of This Information Collection

A final report of the study procedures and results will be issued at the end of the data collection period, as specified in the contract. The results will be presented to FDA management and the report will be made available to the docket and on FDA's website, as part of any future proposed rulemaking on trans fat claims and footnotes. It is anticipated that the findings will be presented in FDA reports and in publications in scientific journals.

A17. Reason for Not Displaying the OMB Approval Date

The OMB Approval Date will be displayed on the questionnaire.

A18. Explanations to Section 19, "Certification for Paperwork Reduction Act Submissions"

No exceptions are requested.

Part B COLLECTION OF INFORMATION USING STATISTICAL METHODS

B1. Universe and Sampling

The study uses an internet panel methodology which has proved substantially equivalent to mall intercept methodologies in that it allows visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. The study will be implemented in a large nationally representative consumer panel with 600,000 households. The consumer mail panel includes consumers who span the full range of education, age, race and income characteristics in the population.

Participants will be adults, age 18 and older, who agree to participate in a study about foods and food labels. Each participant will be randomly assigned to one of the 42 experimental conditions.

B2. Procedures for Collecting the Information

Participants will be asked to thoroughly review the package labeling of products presented to them in pairs and then answer questions about the product's perceived health benefits, choice preferences, risk/benefit tradeoffs, and other questions (see attached questionnaire).

Participants will view two-dimensional color mock-ups of the back of food packages with the major part of the display constituted by the Nutrition Facts Panel. For each product category, participants will see side by side presentations of the back panel of two products and answer a series of product perception (see questionnaire) related to expected health benefits and perceived nutritional characteristics of the products.

In the Full Information condition, respondents will read a one-page summary of the current state of scientific evidence for the health effects of trans fat in the diet. It will be written at a 6^{th}-8^{th}-grade reading level. Nutrition scientists at FDA will review the summaries for accuracy. The Full Information summary will be presented prior to viewing any labels

The key measures for the study are expressed choices between two products described by their nutrition facts panels. The pair of panels presented to a respondent embody one of the seven footnote/cuing schemes to be tested. Respondents are asked to pick the healthier product, report their reasons for their choice, and rate the selected product with respect to perceived nutrition characteristics and expected health benefits.

B3. Methods to Increase or Maximize the Response Rates

Participants are sent multiple reminders asking them to complete the interview instrument. Because participants are practiced at accessing and completing such instruments, no additional measures are necessary.

B4. Tests, Procedures, or Methods Used

The contractor will conduct nine pretests to test procedures. Changes to procedures or the questionnaire will be submitted to OMB prior to data collection.

B5. Identification of Consultation

The contact individuals are Alan S. Levy, Ph.D., Division of Market Studies, Consumer Studies Team, HFS-727, telephone (301) 436-1762 (Project Officer), and Brenda Derby, Ph.D., Division of Market Studies, Consumer Studies Team, HFS-727, telephone (301) 436-1832 (Statistician), and W. Burleigh Seaver, Ph.D., Senior Vice President, Synovate/Market Facts, (703) 790-9099.